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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/502,424	02/11/00	KILIAN	A 191106.407C1

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EXAMINER	
WALICKA,M	
ART UNIT	PAPER NUMBER
1652	4

DATE MAILED:
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/502,424	Applicant(s) KILIAN ET AL.	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

This application, filed on February 11, 2000 is a continuation of application 09/108,401, filled on June 30, 1998. The examiner acknowledges the preliminary amendment filed on February 11, 2000.

Claims 65-107 were added as requested by Applicants. Claims 1-107 are pending and considered in this Office action. The instant Office action substitutes the requirements of restriction/election faxed to the Applicants' representative, J. Silbermann, on June 22, 2001.

A substitute specification is required pursuant to 37 CFR 1.125(a) because preliminary amendment to the specification filed on February 11, 2000, which comprises five pages, was not entered due to its length.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1-15, 27-40, 61, 65-93 and 100-107 drawn to the telomerase gene, its variants, fragments, DNA probes, primers, expression vectors and transformed host cells to produce recombinantly vertebrate telomerase and other polypeptides; classified in class 536 subclasses 23.1, 23.2 and 24.3.

II. Claim 16-22, drawn to vertebrate telomerase, its variants and fragments, classified in class 435, subclass 194.

III. Claim 23-26, drawn to antibody and a hydridoma cell for their production, classified in class 530, subclass 387.9.

IV. Claim 41-45 and 94-97, drawn to a method of diagnosing cancer using telomerase cDNA, classified in class 435, subclass 6.

V. Claim 46-49 and 98-99, drawn to a method of determining a pattern of expression of telomerase RNA, and a method of diagnosing cancer using that pattern; classified in class 435, subclass 6.

VI. Claim 50-53, drawn to transgenic animals where the telomerase gene is operably linked to a promotor effective for the expression of the gene, classified in class 800, subclass 13.

VII. Claim 54, drawn to a mouse having endogenous telomerase gene disrupted, classified in class 800, subclass 9.

VIII. Claim 55-59, drawn to inhibitor of vertebrate telomerase, classified in class 536, subclass 24.5.

IX. Claim 60, drawn to a method of treating cancer, comprising administering therapeutically effective amount of telomerase inhibitor, classified in class 514, subclass 44.

X. Claims 62-64 drawn to a method of identifying an effector of telomerase activity classified in class 435, subclass 6.

Inventions of Group I, II, III, VI, VI and VIII are unrelated because they are independent chemical entities that require independent search of the patent and non-patent literature.

Inventions I, IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, i.e. DNA encoding telomerase and RNA transcribed from it may have many other uses such as in a method to make telomerase.

Invention I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the cloned DNA encoding telomerase and the method of treating cancer comprising administration therapeutically effective dose of inhibitor of telomerase activity are not disclosed as capable of use together as the method of Group IX neither makes nor uses the telomerase gene.

Inventions I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the cloned DNA encoding telomerase is not used in the method of identifying an effector of telomerase activity.

Inventions II, IV, V and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the telomerase and the methods of Group IV, V, and IX are not disclosed as capable of use together and have different modes of operation, different functions and different effects the telomerase of Group II is neither made nor used by the methods of Groups IV, V and IX.

Inventions II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, i.e. the telomerase, may be used in a method to make antibodies.

Inventions III and IV, V, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the antibody that binds telomerase and the method of using telomerase cDNA for cancer diagnosis are not disclosed as capable of use together.

Invention III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody that binds telomerase is not used in the method of treating cancer.

Inventions of Groups IV-VII, IX and X are unrelated. The inventions of Group IV, V, IX and X independent methods having different steps and product. The transgenic animals of Groups VI and VII are not used in any of the methods of Groups IV, V, IX and X.

Group VIII and IX are related as a product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, i.e. an inhibitor of vertebrate telomerase may be use in other process, such as inhibition of telomerase reaction *in vitro* or as an affinity ligand for purification of the telomerase protein.

Inhibitor of Group VIII is unrelated to methods of Group IV, V, and X.

Because inventions I-X are distinct for the reasons given above, acquired a separate status in the art as shown by their different classification, and require a separate searches in the patent and non-patent literature, restriction for examination purposes, as indicated, is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C. F. R. paragraph 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filled petition under 37 C.F.R. paragraph 1.48 (b) and by the fee required under CFR paragraph 1.17(h).

Species election

Claims of Groups I, IV, V and of Group VIII are generic to a plurality of disclosed patentably distinct species comprising DNA molecules encoding amino acid sequences of human telomerase or its variants (SEQ ID NO: 2, 35, 37, 39, 42, 44, 46, 48, 50, 52 - 54, 56-58, 60-62, 64-66, 68-70, 2-74, 76-78, 80-82, 84-86, or the intron sequences: SEQ ID NO:18, 23, 25, 27, 29, 30, 32, and 33).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1600~~
1600